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General discussion
Chapter 7

The central aim of this thesis was to determine the effectiveness and cost-effectiveness of nurse-led problem solving treatment (PST) in primary care for patients with mental health problems who visit the general practitioner (GP). This final chapter discusses the issues that have been raised in previous chapters, beginning with an overview of the main findings concerning the intervention, followed by the general discussion, and results of the trial in light of earlier research. Recommendations for future research and general practice are then outlined, followed by a main conclusion.

Main findings

Concerning the central aim, we concluded nurse-led PST for primary care for patients who suffer from common mental disorders was not more effective than usual care (UC) provided by the general practitioner (Chapter 3). Concerning the post-hoc-analyses, there may be a sub-group of patients with more severe psychopathology who may benefit more from PST than other groups of patients. This finding is applicable to patients who are severely depressed, or having one or more diagnosed disorders (Chapter 3). Regrettably, this effect disappeared in the long term (Chapter 4). As intended, predictors of recovery of common mental disorders were analysed. These analyses led to one predictor of recovery – an age of less than 50-years-old (Chapter 4). In chapter 5 we compared two outcome measures; an expert-derived measurement and a patient-generated measurement. The patient-generated measurement showed a higher sensitivity of change for the patient-generated outcome compared to expert-derived outcome. Finally, the cost-effectiveness of this trial showed no significant difference in costs between both study groups (Chapter 6) but exploration of the cost-effectiveness data showed a tendency for higher costs for the patients in the UC group (Chapter 6).

Adherence to the intervention

PST is protocolized during every session, and it was important to maintain this structure in order to teach the steps of problem solving to the patients. We took several precautionary measures to make sure the intervention is carried out as per protocol. Firstly, L. Mynors-Wallis and I. Davies, who helped
to develop Problem Solving Therapy into PST for primary care, trained the nurses in the trial. They were trained by making use of a treatment manual, a precursor from the later ‘practical guide’ (1). Following training, the nurses treated a number of four ‘pilot’ patients each, while they received supervision from a cognitive-behavioural therapist (CBT) and supervisor. Secondly, these sessions (and all subsequent sessions) were audio taped and the supervisor and the researcher checked completed PST forms. When the nurses were deemed to have treated these ‘pilot’ patients satisfactorily, they began treating patients who participated in the trial. During the trial, the nurses continued to audiotape the sessions, and provide completed PST forms. Every three weeks they participated in a supervision session until the end of the trial. Nurses could always ask for advice in between these sessions, by telephone, e-mail or in person. When the supervisor or researcher concluded that PST was not carried out correctly, additional (individual) supervision sessions were initiated. Therefore, it can be safely stated that PST was carried satisfactorily. However, in every treatment there are so called ‘non-specific variables’, consisting of therapeutic alliance, therapist competence and adherence to specific treatment modality (2). The researches eliminated as much logistical problems as possible to stimulate therapist adherence to the treatment protocol (3;4). Therapeutic alliance can particularly be a contributing factor for effectiveness and seems predictive of treatment outcomes when based on patient perceptions (5-7). Besides our effort, non-specific variables could not be controlled, and could have had either a negative or a positive influence on the results of this trial. In a negative way one could say a lack of alliance could reduce a potential effect or cause dropout, even though intervention was carried out perfectly. In a positive manner these variables could help to not only maximize the potential effect of PST, but also, for example, to improve the affect of the patient.

**Intensity and duration of intervention**

Intensity, frequency and duration of the intervention contribute to a change in outcome. A classic meta-analysis of the relationship between the duration of the intervention and the effect (dose-effect relations) in psychotherapy has been performed by Howard, Kopte, Krause and Orlinsky in 1985 (8). They
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categorized this relationship as a negative function of treatment duration, in which 30% of client made measurable improvement after 2 sessions, 41% after 4 sessions, 53% after 8 sessions, and 62% after 13 sessions (9). By reviewing the literature about dose-effects relationships, two reviews showed the sufficient duration of PST for psychological problems in primary care (10) and for low back pain (11). In earlier studies the optimal amount of PST sessions was approximately six, the median in earlier studies was four (1). This is also in accordance with the results of Howard et al. Therefore, we carried out between four and six sessions. Patients with mental health problems possibly need more PST sessions to fully optimise the effect. Further research is required to determine the ideal amount of sessions of PST for patients with mental health problems.

Perception of intervention by GPs

A recent qualitative study provides an insight into how GPs perceive PST (12). This study showed PST was ‘perceived as being close to current practice approaches and potentially beneficial to both doctor and patient’. One GP verbalized it like:

‘PST is a re-working of an old theme of a common-sense sort of step, I suppose that GPs have been using it all the time, but it is less authoritarian, and it is less authoritative and it gives the patient a sort of a feeling that they are in control of their own treatment’. It was seen not as a complex psychological approach, but as relatively simple, consistent with the pragmatic nature of many GPs. Perceived as under their control, one may ask: could it be harmful? Here are the answers from three different GPs:

‘I can’t see that actual problem solving itself would do harm’

‘You could argue that trying to solve their problems for them could do more harm then actual structured problem solving’

‘I think that on the surface problem solving is really simple but it is very easy to do it not properly I guess whether a GP does it of a psychiatrist or a psychologist I think it is a very effective intervention’.
When attention is paid to the origination of PST and its effectiveness for mentally retarded patients (13) and palliative care (14), in particular, there is no real reason to consider PST is potentially harmful. However, PST is time-consuming for a GP, taking up 3.5 hours per patient. One GP also points out in this article that: *I think that it is a major barrier perception, a lot of GPs say to themselves, ‘I can’t afford to spend that much time with a patient’.* Assistance by Mental Health workers in general practice therefore is still a necessity. Concluding of our trial and former trials (15-17) nurses may be useful to strengthen the primary care and have proven to be perfectly capable to provide PST.

**Contrast between interventions**

The content of the usual care (UC) was not standardized and we do not have information about the extent to which GPs paid attention to mental health problems or in what way they advised patients (no form of treatment was suggested to GPs so as not to reduce the contrast). We assumed that GPs would generally follow the guidelines for anxiety and depression. Although UC in The Netherlands is preferably based on these guidelines, it is not known to exactly what extent GPs follow these guidelines. An observational study, performed by Grol et al. (18) showed that guideline recommendations were followed in an average of 67% of the treatment decisions. This provides little insight into interventions GPs carry out when mental health is an issue. The trial resembled daily clinical practice as closely as possible by applying minimal restrictions on patient selection and GP’s normal care, and so the results are a good general representation of this situation in The Netherlands and other countries with similar health care systems.

**Screening and selection procedure**

Failure to recruit sufficient GPs and patients frequently threatens the progress of research projects in general practice. Often, randomised clinical trials (RCT) have an optimistic calculation of the number of recruited patients and GPs. This over-optimism is called Lasagna’s law (19). The number needed to screen for psychological problems differs in literature. The number needed
to screen is defined as the number of people that need to be screened for a given duration to prevent one adverse event. For example, Rembol (1998) compared directly calculated values with estimated numbers and found that estimated numbers were a fourfold lower (20). Cuijpers ea. (2006) conducted a meta-analysis and found disappointing results for screening for depression in schoolchildren: 1000 to 32, which can be considered quite low (21). By using the screening procedure (described in Chapter 2) in the waiting room, it was possible to include the planned number of patients within the reasonable time period of 18 months, which we estimated. This screening procedure (which took place in the waiting room) is not conventional, and one disadvantage of it could be that patients can feel compelled to participate in the study, with potentially dropout as a consequence. We estimated a drop out at 20% and we calculated a drop out rate of 22% directly after including patients in the trial. This concerns patients who refused to complete the pre test. When patients participated in the trial and completed the pre test, the drop out rate became 6%. Drop out because of social desirability (feeling compelled to participate) could not be rejected. However, an advantage of this procedure is that the GP is relatively unburdened by recruiting patients in the waiting room (the GP would just check the patient’s names in the end of day on exclusion criteria). Also, no additional investment was necessary besides the usual care and the potential biased selection of patients was avoided, by not asking GPs to recruit patients for the study. The selection criteria were not necessarily psychological problems. Therefore, patients with self-limiting problems may have been included. This may have consequences for the external validity of the research, as the group of patients that conclusions may be generalised to, is diffuse. There are two possible solutions for this problem. The first would be to adjust a question about the time frame in the screening. The second would be to invite patients for the first session and only discuss the contract of their treatment. This could possibly make the patient more responsible for his/her treatment and recovery. If patients suffered from mental health problems in the month before entering the trial, spontaneous recovery is usually high within the first 3-6 months (22;23). This could have been avoided by including an explicit question about the duration of the mental disorders. However, this would have the disadvantage of not accurately resembling the patients of clinical practice. Up to this point,
there is no reason to doubt the randomisation of selection criteria. However, when studying cost-effectiveness, higher costs were found for patients in the UC group on baseline, suggesting a randomisation bias (randomisation was carried out by an external researcher). This could be explained by the fact that patients in the UC group suffered from higher morbidity rates than patients in the PST group. Patients in the UC group predominantly reported mostly indirect costs during the trial. According to the results of cost-effectiveness in this study, both absenteeism and presenteeism were included; the latter seemed to form a considerable part of the costs and was not often studied yet. This could explain the difference in results compared to earlier research of cost-effectiveness.

Results of the trial in the light of earlier research

There is evidence that PST can be effective in helping patients to deal with mental health problems (in particular those with depression). In 1995 and 2000 trials on patients suffering from major depression showed PST is as effective as medication (24;25). Earlier trials on patients suffering from mental health problems show the same results in effectiveness (26;27), except one study, were long term outcome for patients who received PST was significantly better(28). Therefore, it can safely be stated that PST is just as good as antidepressants. Until this trial, the effectiveness of PST has been investigated in two systematic reviews (10;11) with overall positive conclusions on its effectiveness. Since then, and besides the trial described in this thesis, three other important studies have taken place.

Firstly, Kendrick et al, 2006 (29), published the results of a trial where nurses conducted PST for patients with mental health problems. The results of this trial resembled those presented in this thesis, with the exception of cost-effectiveness; in the former trial PST was more expensive, but presenteeism was not calculated with indirect costs. Secondly, Cuijpers ea. (2007) performed a meta-analysis on the effectiveness of PST for depression (30). The results of this analysis showed an effectiveness of mean standardized effect-sizes (ES) of 0.34 to 0.83 depending on the model, between PST and control group. The ES calculated for PST only showed the smallest and non-significant ES
compared to other forms of problem-solving (like social problem solving or self-help problem solving). High ES was found for group interventions and with patients who met the criteria for major depression. In a recent review about counselling in primary care for patients with mental health problems, a significantly greater ES (0.28) was found for counselling in the short term compared with usual care. In the long term this effect disappeared (31). This thesis shows that the ES is medium high (not significantly) when calculated separately for PST (0.54) and usual care (0.33) when calculated separately. According to the results of the review, both ES are calculated for short term (three months) and this effect reduces in the long term (nine-months).

Thirdly, a qualitative study about GPs use of PST was undertaken (12). A result of all this new research provides two main insights. Firstly, although PST is an attractive and fairly well researched intervention, it alone is not an effective treatment for all primary care patients with mental health problems other than depression. Secondly, PST is not as effective as was thought at the beginning of this trial, and the results of this study help to delineate the indications for psychological interventions in primary care. The results of this study confirmed short psychological treatment such as PST can serve as a counterpart for care as usual, with modest effects in short term outcome, but provides no additional advantages in the long term. Concerning the patients preference, such an intervention should be available, preferably given by nurses of other general practice assistance.

Nurses can provide these interventions very well. We also think a diagnostic questionnaire should always precede referral for these kind of psychological interventions to guarantee selection of patients who suffers from problems and symptoms that can be effectively treated by these kind of interventions. However, this trial was undertaken due to a lack of evidence-based interventions for patients with mental health problems in primary care (besides the guidelines for depression and anxiety). We expected and confirmed, PST fits in all kinds of primary care. The use of PST could be a clinically relevant tool for GPs as it helps advise patients on how to deal with mental health problems effectively. It can also be used to help patients explain their problems more easily and in more detail, and could also be integrated further in routine care or stepped care.
Recommendations for future research

Firstly, to strengthen the body of evidence for the effectiveness of short, psychological help for patients with common mental health problems in primary care, further research is required. This research should study the definition of sub-groups of patients for whom PST could be effective, or patients who favour PST instead of medication. Secondly, it could be helpful if patients were more aware of their motivation for treatment, and a care approach (in steps) would be recommended to achieve this, like the IMPACT trial, where a depression care manager escorts patients through all the steps undertaken in the weeks that the patient suffers from depression (32). PST is a module in this program, and the effectiveness of this trial is promising. Finally, it is recommended that future research uses primary outcome measurements which not only consist of expert-derived questionnaires, but patient-generated outcomes like the PSYCHLOPS – which was found to be a very useful and sensitive instrument in evaluating psychological treatment in primary care, and as an instrument for stepped care (33).

Recommendations for general practice

Mental health problems are common and are often presented as worries about family, work and income by patients. The GP should be aware of this, and could use PSYCHLOPS as an instrument to promote further studies. Also, patients suffering from major depression could benefit from PST (as indicated in earlier research, although a meta-analysis resulted in low effect-sizes). Patients who prefer counselling instead of drug treatment could be adequately treated using PST, as in this trial PST proved as effective as UC. Finally, this study found nurses to fit in very well in daily practice, and to be enthusiastic about intervention. In future practice nurses should not only be considered as suitable providers of PST, but probably perfectly capable of providing other psychological treatment also.
Main conclusion

This study provides evidence that nurse-led PST is just as effective for all patients with mental health problems as usual care provided by the GP. PST is therefore a good alternative for patients with mental health problems who prefer counselling instead of usual care provided by the GP. Results of this trial suggest, in accordance with earlier research, there could be subgroups of patients in general practice that could benefit more from PST (provided by nurses). More research is needed to identify these subgroups.

Case vignette

In the first PST session Adrian made a list of all his problems and symptoms. Because of his tiredness was decided Adrian would do ‘activity scheduling’ first, to regain some energy and pleasure in life. He walked in the park twice a week en read his favourite book. In the second session Adrian felt better and was aware of the energy he got from doing pleasurable activities. His goal for the second session became: doing pleasurable activities with his wife and his sons. He made a plan to go to the cinema with the whole family. In the third session he worked out a plan to explore the city they moved into, with the whole family. The fourth session he chose the goal to express his feeling about work during an meeting at work. The fifth and last session Adrian decided to look up some of his old friends and make appointments with them.

In the end Adrian’s mood severely improved, as well as his relationship with his wife and children. He was thinking about finding another job in the future.
References


